

§ 558.415

21 CFR Ch. I (4–1–05 Edition)

§ 558.415 Novobiocin.

(a) *Approvals.* Type A medicated articles: 25 grams of activity per pound to 000009 in § 510.600(c) of this chapter. Type B medicated feeds: 17.5 grams per pound to 000009 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.460 of this chapter.

(c) *Conditions of use.* It is used in animal feeds as follows:

(1) *Chickens*—(i) *Amount.* Novobiocin, 6–7 mgs. per lb. body weight per day.

(a) *Indications for use.* Aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount.* Novobiocin, 10–14 mgs. per lb. body weight per day.

(a) *Indications for use.* Treatment of staphylococcal synovitis and generalized staphylococcal infections susceptible to novobiocin.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than 350 grams of novobiocin activity per ton of feed; not for laying chickens; feed 5 to 7 days; withdraw 4 days before slaughter.

(2) *Turkeys*—(i) *Amount.* Novobiocin, 4–5 mgs. per lb. body weight per day.

(a) *Indications for use.* Aid in the treatment of breast blisters associated with staphylococcal infections susceptible to novobiocin.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; not for laying turkeys; feed 5 to 7 days; withdraw 4 days before slaughter.

(ii) *Amount.* Novobiocin, 5–8 mgs. per lb. body weight per day.

(a) *Indications for use.* Aid in the control of recurring outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin following initial treatment with 7–8 mgs. per pound body weight per day.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; feed 5 to 7 days; not for lay-

ing turkeys; withdraw 4 days before slaughter.

(iii) *Amount.* Novobiocin, 7–8 mgs. per lb. body weight per day.

(a) *Indications for use.* Treatment of staphylococcal synovitis and generalized staphylococcal infection susceptible to novobiocin; treatment of acute outbreaks of fowl cholera caused by strains of *Pasteurella multocida* susceptible to novobiocin.

(b) *Limitations.* Administer, as sole ration, feed which contains not less than 350 grams of novobiocin activity per ton of feed; feed 5 to 7 days; not for laying turkeys; withdraw 4 days before slaughter.

(3) *Mink*—(i) *Amount.* 20 mgs. per lb. body weight per day.

(ii) *Indications for use.* For treatment of generalized infections, abscesses, or urinary infections caused by staphylococcal or other novobiocin sensitive organisms.

(iii) *Limitations.* Administer, as sole ration, feed which contains not less than 200 grams of novobiocin activity per ton of feed; feed for 7 days.

(4) *Ducks*—(i) *Amount.* Novobiocin, 350 grams per ton.

(ii) *Indications for use.* Control of infectious serositis and fowl cholera in ducks caused by *Pasteurella anatipestifer* and *P. multocida*, susceptible to novobiocin.

(iii) *Limitations.* Administer, as sole ration, for 5 to 7 days, continue medication for 14 days if necessary, repeat if reinfection occurs; discontinue use at least 3 days before slaughter; not for use in laying ducks.

[40 FR 13959, Mar. 27, 1975, as amended at 45 FR 42263, June 24, 1980; 51 FR 7399, Mar. 3, 1986; 52 FR 36402, Sept. 29, 1987]

§ 558.430 Nystatin.

(a) *Approvals.* Type A medicated articles: 20 grams of activity per pound to 046573 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.470 of this chapter.

(c) *Conditions of use.* It is used for chickens and turkeys as follows:

(1) *Amount.* 50 grams per ton.

(i) *Indications for use.* Chickens and turkeys; aid in control of crop mycosis and mycotic diarrhea (*Candida albicans*).

(ii) *Limitations.* Growing and laying chickens; growing turkeys.

(2) *Amount.* 100 grams per ton.

(i) *Indications for use.* Chickens and turkeys; treatment of crop mycosis and mycotic diarrhea (*Candida albicans*).

(ii) *Limitations.* Growing and laying chickens; growing turkeys; to be fed for 7 to 10 days.

[41 FR 11002, Mar. 15, 1976, as amended at 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 53 FR 40729, Oct. 18, 1988; 55 FR 8461, Mar. 8, 1990; 57 FR 8578, Mar. 11, 1992]

§ 558.435 Oleandomycin.

(a) *Approvals.* Type A medicated articles: 5 grams of activity per pound to 066104 in § 510.600(c) of this chapter.

(b) *Related tolerances.* See § 556.480 of this chapter.

(c) *Special considerations.* Do not use bentonite in Type B or Type C medicated feeds containing oleandomycin. Oleandomycin refers to oleandomycin or feed-grade oleandomycin.

(d) *Conditions of use.* It is used in animal feed as follows:

(1) *Chickens and turkeys*—(i) *Amount per ton.* Oleandomycin, 1 to 2 grams.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency for broiler chickens and growing turkeys.

(2) *Swine*—(i) *Amount per ton.* Oleandomycin, 5 to 11.25 grams.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency in growing-finishing swine.

[40 FR 13959, Mar. 27, 1975, as amended at 44 FR 40283, July 10, 1979; 51 FR 7399, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 66 FR 47963, Sept. 17, 2001]

§ 558.450 Oxytetracycline.

(a) *Approvals.* Type A medicated articles:

(1) 10, 20, 30, 50, 100, and 200 grams per pound to 066104 in § 510.600(c) of this chapter.

(2) 50 and 100 grams per pound to 048164 in § 510.600(c) of this chapter.

(b) *Special considerations.* (1) In accordance with § 558.5 labeling shall bear the statement: "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

(2) The articles in paragraph (a)(1) of this section contain an amount of mono-alkyl (C₈-C₁₈) trimethylammonium oxytetracycline expressed in terms of an equivalent amount of oxytetracycline hydrochloride or an amount of oxytetracycline dihydrate base expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

(3) The articles in paragraph (a)(2) of this section contain an amount of mono-alkyl (C₈-C₁₈) trimethylammonium oxytetracycline expressed in terms of an equivalent amount of oxytetracycline hydrochloride.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d)(1) *Conditions of use.* It is used in feed as follows:

TABLE 1

Oxytetracycline amount	Combination	Indications for use	Limitations	Sponsor
(i) 10 to 20 grams per ton (g/ton).	Sheep; increased rate of weight gain and improved feed efficiency..	066104, 048164
(ii) 10 to 50 g/ton	1. Chickens; increased rate of weight gain and improved feed efficiency..	Do not feed to chickens producing eggs for human consumption.	Do.
.....	2. Growing turkeys; increased rate of weight and improved feed efficiency..	Do not feed to turkeys producing eggs for human consumption.	Do.
.....	3. Swine; increased rate of weight and improved feed efficiency..	Do.
(iii) 100 g/ton	Turkeys; control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to oxytetracycline..	Feed continuously for 7 to 14 days (d); do not feed to turkeys producing eggs for human consumption.	Do.